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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

PONNALURI, PADMASHRI

ART UNIT PAPER NUMBER

1627

DATE MAILED: 12/18/2001

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/654,948

Applicant(s)

Pirrung et al

Examiner

Padmeshri Ponnaluri

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 29, 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 172-209 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 172-209 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5, 7, 11
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

1. This application is a continuation of application 09/557,875.
2. Applicant's election with traverse of species 'a photo lithographic method of making the array', in Paper No. 8, filed on 5/29/01 is acknowledged. The traversal is on the ground(s) that the species election is not a restriction requirement.. Applicants arguments are persuasive and the requirement is made only species election for examination purposes.
3. The species election requirement made on 4/23/01 has been withdrawn upon further search and consideration. All the claims (claims 172-209) will be examined in this application.
4. The preliminary amendment A, filed on 9/1/00; preliminary amendment B, filed on 9/1/00; and preliminary amendment C, filed on 7/9/01 have been fully considered and entered into the application.
5. Claims 1-171 have been canceled and new claims 172-209 have been added by the amendment B, filed on 9/1/00.
6. Claims 172-209 are currently being examined in this application.
7. This application claims priority to several different families of applications. Applicants are requested to clarify the priority applications, since some of the applications are not in the same family.
8. Applicants are requested to update the current status of the parent applications in the specification page 1, line 1.

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9. Applicants petition to correct order of the inventor ship has been considered and granted.

10. This application has been filed with informal drawings. Applicant is invited to notice that boxes 2, 3, 5, 10 and 12 were checked by the draftsman in PTO 948. If applicants plan to amend the drawings or figure numbers, applicants are encouraged to amend the specification so that the description of renumbered figures corresponds to the renumbered figures.

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 172-184, 186, 188-192 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims briefly recite a method of synthesizing a polypeptide array, wherein said array comprises at least two different polypeptides immobilized on a substrate, comprising:
a) contacting said surface with a first protected group; b) contacting the said surface with a second protected amino acid; and c) repeating the above steps until at least two different polypeptides are formed at known location on said substrate surface.

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The specification description is directed to the use of photo lithographic techniques in the methods of making arrays of chemical compounds such as peptides or oligonucleotides, which clearly do not provide an adequate representation regarding the open ended method of synthesizing a polypeptide array of the instant claims. And the use of photo lithographic technique is critical or essential to practice the instant invention.

With regard to the description requirement, Applicants' attention is directed to The Court of Appeals for the Federal Circuit which held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1405 (1997), quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original)[The claims at issue in *University of California v. Eli Lilly* defined the invention by function of the claimed DNA (encoding insulin)].

Although directed to DNA compounds, this holding would be deemed to be applicable to any compound or methods of making the compounds or arrays; which requires a representative sample of methods of making the compounds and/or a showing of sufficient identifying characteristics; to demonstrate possession of the claimed generic(s).

Additionally, the narrow scope of examples directed to photolithography technique in making arrays are clearly not representative of the scope of the claimed method of synthesizing array of polypeptides.

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13. Claims 172-184, 186, 188-192 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for photo lithographic method in protection and deprotection steps of the instant method, does not reasonably provide enablement for the use of other techniques such chemical or magnetic methods. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The instant claims briefly recite a method of synthesizing a polypeptide array, wherein said array comprises at least two different polypeptides immobilized on a substrate, comprising: a) contacting said surface with a first protected group; b) contacting the said surface with a second protected amino acid; and c) repeating the above steps until at least two different polypeptides are formed at known location on said substrate surface.

The specification disclosure does not have a sufficient enabling disclosure for the use of chemical or thermal or magnetic techniques to remove the protecting groups from the compounds so that activated region on the surface is formed.

The factors to be considered in a determination of undue experimentation are disclosed in *In re Wands* (U. S. P. Q. 2d 1400: CAFC 1988) which include: the quantity of experimentation necessary; . the amount of direction or guidance presented; the presence or absence of working examples; . the nature of the invention; the state of the prior art; the predictability of the art; and the breadth of the claims.

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A number of factors would prevent one of ordinary skill in the art from practicing (making and using) the invention without undue experimentation, which are summarized as follows:

- a. The specification fails to give adequate direction and guidance as to the means of synthesizing arrays of polypeptides using techniques other than photolithographic technique. The specification discloses selective deprotection and/or activation with photolithography. The specification discloses that the photo lithographic technique makes it possible to direct light to relatively small and precisely known location on the substrate.
- b. The working examples directed to the use of photo lithographic technique in making arrays of polypeptides or nucleotides.
- c. The breadth of the claims are open-ended regarding method of making the arrays.
- d. The state of the prior art at the time the invention was made is such that synthesis of array of compounds on a substrate, by selective protecting and deprotecting (using chemical or magnetic methods) in general are known to be difficult or unknown.
- e. The art is inherently unpredictable because organic synthesis of peptide array on a substrate and selective protecting and or deprotecting of compounds using chemical or the thermal methods is not possible without using other methods (such as masking using barriers).

In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification, it would take undue trials and errors to practice the claimed invention.

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14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claims 172-209 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 172-184, 186, 188-192 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the claims do not recite how the first selectively activated region or second activated regions are formed. Applicants are requested to include the essential method steps, which are critical in the claimed method.

Claims 172, 174-182, 190-209 are indefinite by reciting 'different polypeptides', clarification is requested what does applicants mean by 'different polypeptides'. It is not clear how the polypeptides are different, does applicants mean that the length of the polypeptides is different or the amino acid composition of the polypeptides is different. Applicants are requested to clarify.

Claim 185 recites the limitation "said step of irradiating" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 187 recites the limitation "said steps of irradiating" . There is insufficient antecedent basis for this limitation in the claim.

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Claim 188 recites the limitation "said steps of irradiating" . There is insufficient antecedent basis for this limitation in the claim.

Claim 189 recites the limitation "said step of irradiating". There is insufficient antecedent basis for this limitation in the claim.

Claim 194 recites 'and combinations thereof', it is not clear what does applicants mean by 'combinations thereof', i.e, it is not clear what is a combination of polystyrene and gallium arsenide.

Claim 195 is indefinite by reciting 'and mixtures thereof', it is not clear whether applicants mean one protecting group has a mixture of the disclosed compounds or does applicants mean the protecting groups can be used in combinations, i.e., amino acids in one area are protected using one type of protecting groups and the other area is protected by a different protecting groups. However, it is not clear from the claim recitation what is mixture thereof.

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 U. S. P. Q. 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 U. S. P. Q. 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 U. S. P. Q. 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 U. S. P. Q. 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 172-209 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 5,405,783.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims 172-192 (broad) do not use photo removable protecting groups, as recited by the reference method claims. However, the instant array of polypeptides could not have prepared using other types of protecting groups.

18. Claims 172-209 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 5,143,854.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the '854 patent claims are drawn to a method of identifying a polypeptide, however, the method of identification includes the method of synthesis of the polypeptide array on a substrate..

19. Claims 172-209 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 5,384,261. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '261 patent claims recite a method of forming a plurality of peptide sequences on a surface, and uses a channel block to block for forming selective regions of activated regions. The instant method is broad and would the use the channel block of the '261 patent..

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20. Claims 172-209 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2, 4, 6, 10 of U.S. Patent No. 6,329,143. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '143 patent claim recites a method which uses a electric field to remove the protecting group. The instant claimed method is broad and would encompass the '143 patent method.

21. Claims 172-209 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10-12, 15-19, and 24 of copending Application No. 08/563,759. Although the conflicting claims are not identical, they are not patentably distinct from each other because the 08/563,759 application claims are directed to binary synthesis. And the instant claim methods are broad and would encompass the binary synthesis method of the reference application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

It is noted by the examiner that this application is related to several families of applications (i.e., same inventive entity or same assignee). Several of these applications have related subject matter. The examiner is unable to obtain all the pending cases to determine the double patenting. Applicants are requested to provide a list of application which may have potential double patenting with this application.

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22. No claims are allowed.

23. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Ponnaluri whose telephone number is (703) 305-3884. The examiner can normally be reached on Monday to Thursday from 6.30 AM to 4.00 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat, Ph.D., can be reached on (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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PADMASHRI PONNALURI
PRIMARY EXAMINER